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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 6,028,071. The application was filed on November 19, 2009, under 35 U.S.C. § 156.

The patent claims the human drug product FOLOTYN®, a method of using FOLOTYN® and a pharmaceutical composition comprising FOLOTYN®. FOLOTYN® was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Marina Larson
Larson & Anderson, LLC
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Dillon, CO 80435-4928

RE: FOLOTYN® (pralatrexate)
Docket No. FDA-2010-E-0030